

107TH CONGRESS  
2D SESSION

# S. 2049

To amend the Federal Food, Drug and Cosmetic Act to include a 12 month notification period before discontinuing a biological product, and for other purposes.

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## IN THE SENATE OF THE UNITED STATES

MARCH 21, 2002

Mr. DEWINE (for himself, Mrs. CLINTON, and Mr. DODD) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

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## A BILL

To amend the Federal Food, Drug and Cosmetic Act to include a 12 month notification period before discontinuing a biological product, and for other purposes.

1       *Be it enacted by the Senate and House of Representa-*  
2       *tives of the United States of America in Congress assembled,*

3       **SECTION 1. SHORT TITLE.**

4       This Act may be cited as the “Childhood Vaccine  
5       Supply Act of 2002”.

1 **SEC. 2. AMENDMENTS TO THE FEDERAL FOOD, DRUG, AND**  
2 **COSMETIC ACT.**

3 (a) INCLUSION OF BIOLOGICAL PRODUCTS.—Section  
4 506C(a) of the Federal, Food, Drug, and Cosmetic Act  
5 (21 U.S.C. 356c(a)) is amended—

6 (1) in the matter preceding paragraph (1) by  
7 striking “that is the sole manufacturer of a drug”  
8 and inserting “of a product regulated by the Food  
9 and Drug Administration”;

10 (2) in subparagraph (C) of paragraph (1), by  
11 striking “of a debilitating disease or condition;” and  
12 inserting “or treatment of a serious disease or condi-  
13 tion; and”;

14 (3) in paragraph (2), by striking “; and” and  
15 inserting “, or for which a biologics license applica-  
16 tion has been approved under section 351 of the  
17 Public Health Service Act;”;

18 (4) by striking paragraph (3); and

19 (5) in the flush matter at the end, by striking  
20 “of the drug at least 6 months” and inserting “, in  
21 the case of a product approved under section 505(b)  
22 or 505(j), at least 6 months, or in the case of a  
23 product approved under section 351 of the Public  
24 Health Service Act, at least 12 months”.

1 (b) REDUCTION IN NOTIFICATION PERIOD.—Section  
2 506C(b) of the Federal Food, Drug, and Cosmetic Act (21  
3 U.S.C. 356c(b)) is amended—

4 (1) in paragraph (1), by striking “6-month pe-  
5 riod” and inserting “notification period prescribed in  
6 subsection (a)”;

7 (2) in paragraph (2), by striking “6-month pe-  
8 riod” and inserting “notification period prescribed in  
9 subsection (a)”;

10 (3) in paragraph (3), by striking “6-month pe-  
11 riod” and inserting “notification period prescribed in  
12 subsection (a)”;

13 (4) in paragraph (4), by striking “6-month pe-  
14 riod” and inserting “notification period prescribed in  
15 subsection (a)”;

16 (5) in paragraph (6), by striking “of the drug  
17 involved for 6 months” and inserting “of the product  
18 approved under section 505(b) or 506(j), for 6  
19 months, or the product approved under section 351  
20 of the Public Health Service Act, for 12 months”.

21 (c) DISTRIBUTION.—Section 506C(c) of the Federal  
22 Food, Drug, and Cosmetic Act (21 U.S.C. 356c(c)) is  
23 amended by inserting “, hospital,” after “physician”.

1 **SEC. 3. AMENDMENT TO THE PUBLIC HEALTH SERVICE**  
2 **ACT.**

3 Section 317(j) of the Public Health Service Act (42  
4 U.S.C. 247b(j)) is amended by adding at the end the fol-  
5 lowing:

6 “(3) The Secretary may purchase pediatric and adult  
7 vaccines for national stockpiles utilizing a portion of the  
8 funds made available under this subsection.”.

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